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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,977	12/10/2001	Michael Evan Webber	260/289	3321

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LOS ANGELES, CA 90013-1025

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,977

Applicant(s)

WEBBER, MICHAEL EVAN

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-11,13,14,17-22,24-26,29-34,36,37 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-11,13,14,17-22,24-26,29-34,36,37 and 3942 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 13, 14, 25, 26, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification recites that the threshold level is 3.5-5.5% for carbon dioxide. However, the discussion as to the variable threshold states that the threshold is 0.5% below the highest carbon dioxide level from the previous breath or 0.5 above the lowest level from the previous breath. In the instance where, for some reason, the previous breath's highest level was 3% or below or the lowest level was 2.5% or below, the updated threshold would, according to the specification be 3.0% or below. Hence, the specification does not provide support for a variable (update based on previous measurements) threshold that is at least 3.5% or 4.5%, as recited in these claims. Since this is an amended claim, the amendment introduces new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 8-11, 13, 14, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention. Claims 1, 4-6, 8, 10, 13, 14, and 17-19 are rejected in that the independent claims 1 and 11 recite measuring the first component by means of . . . The word means has a very specific meaning in the US patent system, as defined by 112 sixth paragraph. The use of the phrase by means of in the current instance makes it unclear whether applicant is attempting to invoke the sixth paragraph of 35 U.S.C. 112. Applicant should amend the claims to substitute the word "using" or other similar words for the phrase by means of.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8, 10, 11, 13, 14, 17, and 19 are rejected under 35 U.S.C. 103(a) as being obvious over Kiefer et al in view of Forrester et al and Culver et al. With respect to claims 1, 4-6, 8, 10, 11, 13, 14, 17 and 19, Kiefer teaches method of analyzing alveolar breath by expiring breath into a chamber, continuously monitoring the concentration of carbon dioxide in the expired breath with a detector 17, and when the carbon dioxide level reaches 4.5%, triggering the measurement of alcohol concentration in the alveolar breath. Neither the carbon dioxide nor the alcohol measurements are done optically. Forrester et al further teaches a similar measuring arrangement using the carbon dioxide concentration to trigger the measurement of alcohol concentration,

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where both the carbon dioxide and alcohol levels are done optically. Hence, it would have been obvious to modify Kiefer et al to use optical measurements, as it is merely the substitution of one known equivalent sensing method for another. The combination does not base the trigger threshold on previous measurements. Culver et al teaches a breath monitoring device where a threshold is update based on previous patient measurements, to tune the device to the particular patient. Hence, it would have been obvious to modify the above combination to update the threshold based on previous measurements, in order to allow the device to be fine tuned to each patient.

Claims 20, 21, 22, 24-26, 29, 31-34, 36, 37, 39, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiefer et al in view of Forester et al and Culver et al as applied to claims 1, 4-6, 8, 10, 11, 13, 14, 17, and 19 above, and further in view of Gratton et al. With regard to claims 20, 21, 22, 24-26, 29, 31-34, 36, 37, 39, 40, and 42, the only remaining difference is that applicant recites that the two light signals are multiplexed. Gratton et al teaches in figure 4, that which is well known in this field, i.e. that it is known to multiplex signals of different wavelengths for measurement. Hence, it would have been obvious to modify the above combination to multiplex the signals, as it is the substitution of one equivalent measurement technique for another.

Claims 1, 4-6, 8, 9, 11, 13, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Gustafsson et al et al in view of Kiefer, Forrester et al and Culver et al. With respect to claims 1, 4-6, 8, 9, 11, 13, 14, 17 and 18, Gustafsson teaches a method of measuring NO in alveolar air using spectrophotometric techniques. It does

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not teach a method of ensuring that only alveolar breath components are measured.

Kiefer teaches method of analyzing alveolar breath by expiring breath into a chamber, continuously monitoring the concentration of carbon dioxide in the expired breath with a detector 17, and when the carbon dioxide level reaches 4.5%, triggering the measurement of alcohol concentration in the alveolar breath. The carbon dioxide measurement is not done optically. Forrester et al further teaches a similar measuring arrangement using the carbon dioxide concentration to trigger the measurement of alcohol concentration, where the carbon dioxide levels are measured optically. Hence, it would have been obvious to modify Kiefer et al to use optical measurements, as it is merely the substitution of one known equivalent sensing method for another. The combination does not base the trigger threshold on previous measurements. Culver et al teaches a breath monitoring device where a threshold is update based on previous patient measurements, to tune the device to the particular patient. Hence, it would have been obvious to modify the above combination to update the threshold based on previous measurements, in order to allow the device to be fine tuned to each patient.

Claims 20, 21, 22, 24-26, 29, 30, 32-34, 36, 37, 39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafsson et al in view of Kiefer et al and Forester et al and Culver et al as applied to claims 1, 4-6, 8, 9, 11, 13, 14, 17, and 18 above, and further in view of Gratton et al. With regard to claims 20, 21, 22, 24-26, 29, 30, 32-34, 36, 37, 39, 40, and 41, the only remaining difference is that applicant recites that the two light signals are multiplexed. Gratton et al teaches in figure 4, that which is well known in this field, i.e. that it is known to multiplex signals of different

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wavelengths for measurement. Hence, it would have been obvious to modify the above combination to multiplex the signals, as it is the substitution of one equivalent measurement technique for another.

Applicant's arguments filed 7/21/2003 have been fully considered but they are not persuasive.

Applicant has asserted that the teachings of Culver are not relevant to Kiefer and Forrester, as Culver does not concern updating the trigger threshold for carbon dioxide used to measure alveolar breath components. The examiner notes that Culver teaches what is old and well known in the medical art, that it is known to update thresholds based on the specific patient data, to accommodate patient anomalies in each measurement. The fact that Culver is not exactly the same as the claimed invention or the references is not relevant to prosecution, as the Federal Circuit has made it clear that a reference is good for all it teaches.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

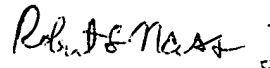
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
October 4, 2003

ROBERT L. NASSER
PRIMARY EXAMINER